

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

TERRESKI MULLINS, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-02952

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION & ORDER**  
*(Motions to Clarify)*

Pending before the court are defendants' Objection to PTO # 182 and Motion to Clarify [Docket 27] and plaintiffs' Motion for Clarification Regarding Pretrial Order # 182 [Docket 28]. To the extent these motions seek clarification, they are **GRANTED**. Below, I address the defendants' objections and further clarify the scope of the consolidated trial.

**I. Clarification of Pretrial Order # 184**

On June 12, 2015, I entered Pretrial Order ("PTO") # 182, which consolidated twenty-six West Virginia TVT cases for trial on the issues of negligent design defect and strict liability design defect. (PTO # 182, *In re: Ethicon, Inc., Pelvic Repair System Prods. Liab. Litig.*, No. 2:12-md-2327, entered June 12, 2015, *available at* <http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html>). When the parties advised the court that some of the included cases concerned products other than the TVT, I vacated PTO # 182, (PTO # 183, *In re: Ethicon, Inc., Pelvic Repair System Prods. Liab. Litig.*, No. 2:12-md-2327, entered June 30, 2015, *available at* <http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html>), and entered PTO # 184, eliminating the non-TVT plaintiffs and ultimately consolidating thirty-seven West Virginia TVT cases. (PTO

# 184 [Docket 25]). PTO # 184 also clarifies the scope of the consolidation. Whereas PTO # 182 suggests that the above-styled cases are to be consolidated on the claims of negligent design and strict liability design defect in their entirety, PTO # 184 explains that the consolidation is of one element of these claims, namely, the element related to defective design. (*See id.* (“[T]he above-styled actions are consolidated for trial on the defective design element of the plaintiffs’ negligent design and strict liability design defect claims.”)).

A review of West Virginia product liability law sheds light on my intentions for this consolidated trial and will aid in the parties’ trial preparation. With respect to the claim of strict liability design defect, the starting point is, of course, *Morningstar v. Black & Decker Manufacturing Co.*, 253 S.E.2d 666 (W. Va. 1979). *Morningstar* explains that a defective product “may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural [or manufacturing] defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions, and labels.” *Id.* at 682. The court defines “defectiveness” with three syllabus points that have since become the crux of strict liability law in West Virginia:

4. In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is *not reasonably safe for its intended use*. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer’s standards should have been at the time the product was made.

5. The term “unsafe” imparts a standard that the product is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to economic costs, at the time the product was made.

6. The question of what is an intended use of a product carries with it the concept of all those uses a reasonably prudent person might make of the product, having in mind its characteristics, warnings and labels.

*Id.* at Syl. pts. 4–6 (emphasis added). If the plaintiff can show that the product was defective when it left the manufacturer and that the defect proximately caused her injury, “a recovery is warranted.” *Id.* at 680.

For the strict liability category of design defect, *Morningstar*’s test can be tapered into three discrete elements: (1) the design of the product at issue is defective in the sense that it renders the product not reasonably safe for its intended use, and (2) the defect proximately caused (3) the plaintiff’s injury. This consolidated trial will focus exclusively on the first element. In other words, the jury will be charged with the following question: Does the design of the TVT make the product not reasonably safe for its intended use?

As indicated in *Morningstar*, the first element involves several sub-issues that the parties should be aware of and consider in their preparations. First, reasonable safeness is measured by the design standards of a “reasonably prudent manufacturer.” *Id.* at Syl. pt. 4. Second, the relevant design standards are those existing “at the time the product was made.” *Id.* And finally, in evaluating the reasonable safeness of the product, the fact-finder must weigh other considerations, including the “general state of the art of the manufacturing process” at the time the product was made; the product’s design, labels, and warnings; and economic costs. *Id.* at Syl. pt. 5.<sup>1</sup>

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<sup>1</sup> This last sub-issue is West Virginia’s version of the risk-utility analysis employed by several other states, in which design defect is determined by balancing the product’s risk of harm against the costs of reducing that risk. In *Morningstar*, the court explains that “a risk/utility analysis [has] a place in a tort product liability case by setting the general contours of relevant expert testimony concerning the defectiveness of a product.” *Morningstar*, 253 S.E.2d at 682. As an example of risk-utility analysis, the court refers to New Jersey’s seven-factor test for determining if a product is defective. *See id.* at 681–82 (quoting *Cepeda v. Cumberland Eng’g Co., Inc.*, 386 A.2d 816 (N.J. 1978)). Some West Virginia courts have used this seven-factor test to explain to the jury the “not reasonably safe” standard set forth in *Morningstar*, an approach that the West Virginia Supreme Court of Appeals accepts. *See In re Tobacco Litig.*, No. 13-1204, 2014 WL 5545853, at \*2–3 (W. Va. Nov. 3, 2014) (allowing the circuit court to use New Jersey’s seven-factor test to explain *Morningstar*’s “not reasonably safe” standard to the jury). But because the “seven-factor risk/utility analysis [] is not easily susceptible to a jury instruction,” *Morningstar*, 253 S.E.2d at 682, I will not assume this approach. Instead, I will instruct the jury using the language of *Morningstar*’s Syllabus Point 5 with an accompanying instruction that the jury “may consider the utility of the design against potential risks of the

West Virginia’s law on negligence illustrates that the breach element of the plaintiffs’ negligent design claim easily fits within the defective-design analysis and, as a result, the scope of this consolidation. Pulling from the general formulation of negligence, the claim of negligent design requires proof that (1) the manufacturer owed the plaintiff, as a consumer, a duty to act like a reasonably prudent manufacturer in designing its products;<sup>2</sup> (2) the manufacturer breached this duty by failing to conform to the design standards of a reasonably prudent manufacturer in designing its products; and (3) the manufacturer’s breach proximately caused (4) injury to the plaintiff. *See, e.g., Strahin v. Cleavenger*, 603 S.E.2d 197, 205 (W. Va. 2004) (“To prevail in a negligence suit, the plaintiff must prove by a preponderance of the evidence that the defendant owed a legal duty to the plaintiff and that by breaching that duty the defendant proximately caused the injuries of the plaintiff.”). This consolidated trial will focus on the second element, whether Ethicon breached the duty owed to the plaintiffs to design the TVT as a reasonably prudent manufacturer would.

One can see how the evidence on breach of duty—which considers whether the defendant’s actions conformed to the design standards of a reasonably prudent manufacturer—would mirror, or at least overlap with, the evidence on defective design—which considers, in part, whether the defendant’s actions conformed to the design standards of a reasonably prudent manufacturer. *See Morningstar*, 253 S.E.2d at Syl. pt. 4. As a result, the discovery required to prepare for the strict liability aspect of the consolidated trial should not differ from the discovery required to prepare for the negligence aspect. *See infra* at 11 (discussing the similarities between

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harm created.” (*See, e.g.,* The Court’s Charge & Instructions, *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-8633 [Docket 539], at 16–17).

<sup>2</sup> Whether a defendant owed the plaintiff a duty of care is not a question of fact but a determination that must be rendered by the court as a matter of law. *Strahin v. Cleavenger*, 603 S.E.2d 197, 201 (W. Va. 2004). I **FIND** as a matter of law that Ethicon owed a duty to the plaintiffs, as consumers, to design its product in accordance with the standards of a reasonably prudent manufacturer.

the risk-utility test and the standard for negligence).

As a last note, I emphasize to the parties that the consolidated trial will only involve the narrow and discrete issues outlined above. These are universal, non-specific issues concerning the design of the TVT and whether that design was reasonably safe. Determining reasonable safeness necessarily involves consideration of the TVT's capability to cause injury. As a result, causation will be relevant to the consolidated trial but only in the general sense. *See, e.g., Meade v. Parsley*, No. 2:09-cv-00388, 2010 WL 4909435, at \*5 (S.D. W. Va. Nov. 24, 2010) (comparing general causation, i.e., "whether a substance is capable of causing a particular injury or condition in the general population," with specific causation, i.e., "whether a substance caused a particular individual's injury"). In other words, the pertinent issue will be whether the TVT *can* cause injury (general causation), not whether it *did in fact* cause injury to a particular plaintiff (specific causation). Plaintiff-specific evidence is not required for general causation, nor will it be accepted. Rather, the parties' primary focus should be the scientific and medical literature suggesting or contesting that the TVT is defectively designed in that it is not reasonably safe and can cause harm to women who are implanted with it. *See id.* Then, if the consolidated trial is decided in the plaintiffs' favor, a second phase of trials will take place regarding the individualized aspects of the plaintiffs' claims left out of the consolidation (specific causation and injury).<sup>3</sup> During the second phase, the plaintiffs can also pursue their other claims against Ethicon.<sup>4</sup>

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<sup>3</sup> Because the malfunction theory, if it applies, relates to specific causation, I need not address it at this stage. The parties are free to raise the issue again during the second phase of trials.

<sup>4</sup> In their Motion for Clarification, the plaintiffs argue that the case of *Ilosky v. Michelin Tire Corp.*, 307 S.E.2d 603 (W. Va. 1983), provides a right under West Virginia law for a plaintiff to have all her claims heard together by a single jury. This argument misreads *Ilosky*, which nowhere states, either expressly or impliedly, that all claims must be presented to the same jury at the same time. In any event, the order and manner in which claims are presented to the jury is a procedural matter subject to federal law, not West Virginia law. Moreover, the true holding of *Ilosky* is preserved by PTO # 184. The *Ilosky* court held that after evidence has been presented to the jury on various causes

Having clarified the scope of the consolidated trial, I now turn to Ethicon's specific objections to consolidation.

## **II. Ethicon's Objections**

Ethicon raises five objections to consolidation: (1) the issue of design defect liability cannot be decided in a consolidated trial because the trial "will lack the otherwise required finding that a defect existed in an individual plaintiff's device and proximately caused her injuries"; (2) the issue of product warnings, not included in the consolidated trial, "may be relevant in cases where Ethicon asserts its Section 402A, comment k defense to design defect liability"; (3) proof of safer alternative design requires plaintiff-specific evidence; (4) "a trial that attempts to determine design defect liability in the absence of individualized proof" violates Federal Rules of Evidence 402 and 403; and (5) a determination of defect liability in the first phase of trial will violate Ethicon's constitutional rights under the Fifth and Seventh Amendments. (Defs.' Objection to PTO # 182 & Mot. to Clarify ("Defs.' Objection") [Docket 27], at 3–4).

### **1. Plaintiff-Specific Product Defects and Proximate Cause**

Ethicon first argues that a consolidated trial on design defect liability would lack the required findings "that a defect existed in an individual plaintiff's device and proximately caused her injuries." (*Id.* at 3). As an initial matter, because the consolidated plaintiffs received the same type of device with the same design, it is not necessary to evaluate whether a defect existed in each of their individual implants. Furthermore, as explained above, the consolidated trial is not on design defect *liability* but instead on the existence of a design defect or defects in the TVT

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of action, the plaintiffs cannot be "force[d] to choose one theory to submit to the jury." 307 S.E.2d at 613. Otherwise, the court explained, the plaintiffs would have to "forego the strict liability cause of action if they believed they had stronger negligence or warranty cases." *Id.* PTO # 184 does not force plaintiffs into one theory of product liability or require them to forgo their failure to warn claim, for example, in favor of their design defect claim. The plaintiffs are free to pursue their other claims during the second phase of trials.

and whether Ethicon acted as a reasonably prudent manufacturer in designing the TVT. This inquiry does not concern specific causation or Ethicon's ultimate liability for the claim of design defect, which would be determined in the second phase of the trials. Accordingly, Ethicon's first objection fails.

## **2. Comment k Defense**

Next, Ethicon contends that "the issue of product warnings may be relevant in cases where Ethicon asserts its Section 402A, comment k defense to design defect liability." (Defs.' Objection [Docket 27], at 3). After reviewing the origin and purpose of section 402A in light of the transformation of strict product liability law over the past fifty years, I find comment k unnecessary in West Virginia and therefore immaterial to the issue of consolidation.

### **a. Restatement Section 402A**

Section 402A of the Restatement (Second) of Torts ("Restatement" or "Second Restatement") is the archetype of modern strict product liability, stating that a seller may be liable for "unreasonably dangerous" products in a "defective condition that cause physical harm." Restatement § 402A (1965). At the time of the Second Restatement's publication in 1965, the field of strict product liability was a newly emerging area of the law. Justice Traynor's influential opinion in *Greenman v. Yuba Power Products, Inc.* had recently been issued, which dispensed with the old theories of warranty and established the doctrine of strict product liability in tort. 377 P.2d 897, 901 (Cal. 1963). In the following years, the American Law Institute ("ALI") wrote section 402A to represent *Greenman's* modern view.

As a result, section 402A became more than a mere "restatement" of the law; instead, it represented a "sweeping reform" that "was embraced by courts '[w]ith a gusto unmatched in the annals of the Restatements of the Law.'" Geoffrey Christopher Rapp, *Torts 2.0: The Restatement 3rd and the Architecture of Participation in American Tort Law*, 37 Wm. Mitchell L. Rev. 1582,

1589 (2011) (quoting David G. Owen, *Design Defect Ghosts*, 74 Brook. L. Rev. 927, 935 (2009)); accord John H. Chun, *The New Citadel: A Reasonably Designed Products Liability Restatement*, 79 Cornell L. Rev. 1654, 1657 (1994) (“402A did not restate existing law, but rather proposed a new solution to then existing problems, sparking a significant change in plaintiffs’ prospects for recovery.”). Indeed, “[t]ort law has probably never witnessed such a rapid, widespread, and altogether explosive change in the rules and theory of legal responsibility. If ever a Restatement reformulation of the law were accepted uncritically as divine, surely it was section 402A of the Restatement (Second) of Torts.” Owen, *supra*, at 935.<sup>5</sup> Despite its enthusiastic adoption, section 402A has not aged well since 1965. As strict product liability law has developed over the past fifty years, the shortcomings of section 402A have come to the forefront.

Section 402A’s most significant shortcoming is that it only provides for a consumer-expectations test: “The rule stated in this Section applies only where the product is, at the time it leaves the seller’s hands, in a condition *not contemplated by the ultimate consumer*, which will be unreasonably dangerous to him.” Restatement § 402A cmt. g (emphasis added); *see also id.* cmt. i (“The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it . . . .”). In other words, under the consumer-expectations test, a product is defective “if [it] has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.” *Barker v. Lull Eng’g Co.*, 573 P.2d 443, 446 (Cal 1978). For example, in applying the consumer-expectations test to food products, one court found that a defendant could be liable for injuries

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<sup>5</sup> Contrast the swift and largely uncritical adoption of section 402A of the Second Restatement with the hesitant adoption—or, in some cases, outright rejection—of the Restatement of Torts (Third): Products Liability (“Third Restatement”). *See, e.g., Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (“We conclude that § 6(c) has no basis in the case law. . . . [W]e do not adopt § 6(c) of the Third Restatement.”).



caused by an unidentified foreign object in a pumpkin muffin, noting that “a sharp pain and choking sensation” is not “the kind of event that an ordinary consumer would anticipate and guard against” while eating a muffin. *Schafer v. JLC Food Sys., Inc.*, 695 N.W.2d 570, 575–77 (Minn. 2005); *see also Mitchell v. BBB Servs. Co.*, 582 S.E.2d 470, 471–72 (Ga. Ct. App. 2003) (finding that a defendant could be liable for injuries caused by a bone fragment in a hamburger because “a jury could reasonably determine that . . . a consumer of the meat should not reasonably have anticipated the bone’s presence” (quoting *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 452 (N.C. 1992))).

While this test often works well in the context of manufacturing defects, it is often an ill fit when considering a claim for design defect. *See* Dan B. Dobbs et al., 2 *The Law of Torts* § 453 (2d ed. 2011) (“The test has worked especially well in the case of non-obvious product flaws, as distinct from design defects.”). In some instances, the test is overinclusive, such that any injury suffered by a consumer can demonstrate a defect. *Id.* § 455; *see also, e.g., Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (employing a consumer-expectations test so broad that a showing of causation alone was sufficient to prove defect). Yet in other instances, the test is underinclusive. Open and obvious dangers can defeat otherwise meritorious claims of design defect simply because, for example, a consumer does not expect safety in a product that lacks safety features, even if those features could be added cheaply and easily. Dobbs et al., *supra*, § 455; *see also, e.g., Vineyard v. Empire Mach. Co.*, 581 P.2d 1152, 1155 (Ariz. Ct. App. 1978) (deciding that a twenty-ton earth-moving machine that rolled over and crushed plaintiff’s leg was not defective because absence of roll-over bars was “immediately evident”).

The test also fails to take into account the risk of injury to bystanders. David G. Owen et al., 1 *Madden & Owen on Products Liability* §§ 5:6, 8:3 (3d ed. 2000); *see also, e.g., Horst v.*

*Deere & Co.*, 769 N.W.2d 536, 540 (Wis. 2009) (determining that a lawnmower that severed the feet of a two-year-old child was not defective, even though injury would have been prevented through a simple design alteration, because the lawnmower performed as expected by user). A more fundamental problem with the consumer-expectations test is that, for many products, “the consumer would not know what to expect, because he would have no idea how safe the product could be made.” John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 829 (1973). This is likely to occur in cases involving technologically complex products, such as a fuel-injection engine or an airbag. *See Ray ex rel. Holman v. BIC Corp.*, 925 S.W.2d 527, 531 (Tenn. 1996); Douglas A. Kysar, *The Expectations of Consumers*, 103 Colum. L. Rev. 1700, 1716 (2003).

Because the consumer-expectations test proved to be largely unworkable for design defects, the vast majority of courts have now adopted the risk-utility test. *See Branham v. Ford Motor Co.*, 701 S.E.2d 5, 14 (S.C. 2010) (counting thirty-five out of the forty-six states that recognize strict liability to have adopted the risk-utility test in some form). The risk-utility test for design defect finds its origins in the early 1970s. *See Wade, supra*, at 837–38; Page Keeton, *Product Liability and the Meaning of Defect*, 5 St. Mary’s L.J. 30, 38 (1973). Generally speaking, the test provides that a product’s design is defective if its risks exceed its utility. *Barker*, 573 P.2d at 454. There are a number of factors to consider when evaluating risk and utility, and the seven-factor test posed by Professor John W. Wade has been highly influential in courts throughout the country. *See Wade, supra*, at 837–38; Dobbs et al., *supra*, § 456.<sup>6</sup> The Third Restatement has likewise adopted the risk-utility test. *See Third Restatement* § 2 cmt. f.<sup>7</sup>

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<sup>6</sup> As noted above, New Jersey is a state that has adopted the seven-factor test. *See supra* at 5 n.1. The seven factors are

(1) The usefulness and desirability of the product—its utility to the user and to the public as a

The risk-utility test represents a doctrinal change in the law of strict liability. In particular, the risk-utility test in strict product liability bears a striking resemblance to the principles of negligence. *See* Restatement § 291 (“Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.”); *see also United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (providing for negligence using the Hand formula, which finds a breach of duty if the probability of injury multiplied by its cost exceeds the burden of adequate preparations). It is no surprise, then, that under the risk-utility test, “nominal strict liability now appears to most observers to be ordinary negligence liability traveling under the name of strict liability[.]” Dobbs et al., *supra*, § 456. Although a few courts have accepted that claims for strict liability and negligence have analytically merged, many courts continue to resist calling a spade a spade and “tak[ing] the final step to acknowledge that negligence doctrine should displace strict liability as the single, proper liability standard for rendering risk-utility determinations in design defect cases.” Owen et al., *supra*, § 2:9.

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whole. (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user’s ability to avoid danger by the exercise of care in the use of the product. (6) The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Wade, *supra*, at 837–38. The first six factors relate specifically to the risks and utility of a product, while the seventh factor addresses “the overall policy of imposing strict liability. To the extent that the risk-utility approach dissolves strict liability into negligence law, this seventh factor now seems to have little if any relevance.” Dobbs et al., *supra*, § 456; *cf. Fiorino v. Sears Roebuck & Co.*, 707 A.2d 1053, 1057 (N.J. Super. Ct. App. Div. 1998) (“[T]he seventh factor should almost never be charged to the jury.”).

<sup>7</sup> The Third Restatement’s approach is slightly different in that the plaintiff generally must show a reasonable alternative design to prevail on a design-defect claim. *See* Third Restatement § 2 cmt. f. But determining the reasonableness of a proffered alternative design entails application of the risk-utility test. *See id.*

Yet even before the widespread shift to the risk-utility test beginning in the 1970s, at least some of the drafters of the Restatement believed that prescription drugs should be exempt from strict liability evaluation under the consumer-expectations test. *See* Am. Law Inst., *Wednesday Afternoon Session*, 38 A.L.I. Proc. 90–98 (1961). But instead of including such an exemption in section 402A itself, the drafters crafted a confusing exception in the comments: comment k.

#### **b. Comment k**

Comment k of section 402A provides a defense for certain “[u]navoidably unsafe products.” Because this comment has been the subject of much confusion for courts, litigants, and commentators, I provide it in full:

*k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement § 402A cmt. k. (emphasis in original).

The language of comment k is undeniably vague and abstruse. One commentator noted that the vagueness reflects “the murkiness of its origins” in discussions of the ALI on the

application of section 402A to prescription drugs. Joseph A. Page, *Generic Product Risks: The Case Against Comment K and for Strict Tort Liability*, 58 N.Y.U. L. Rev. 853, 866 (1983). Other commentators have called comment k “truly an enigma.” James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 Cornell L. Rev. 1512, 1542 (1992). Courts’ conflicting interpretations have done little to remedy the confusion.<sup>8</sup>

An uncontroversial—but exceedingly significant—aspect of comment k is that it contains a risk-utility test: a product such as the rabies vaccine has great risks but even greater utility such that a manufacturer should not be liable for injuries that may result from it.<sup>9</sup> Thus, because comment k assumes that for these *unavoidably* unsafe products, there exists some baseline level of risk that cannot be reduced, comment k’s risk-utility test can be viewed as a variation of the general risk-utility test.

As mentioned earlier, the vast majority of courts already employ the risk-utility test in some form, without regard to comment k, based on the inadequacies that scholars have identified in use of the consumer-expectations test. *See, e.g., Barker*, 573 P.2d at 454 (citing *Wade, supra*); *Henderson v. Ford Motor Co.*, 519 S.W.2d 87, 92 (Tex. 1974) (citing, inter alia, *Keeton, supra*), *overruled on other grounds by Turner v. Gen. Motors Corp.*, 584 S.W.2d 844 (Tex. 1979), and

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<sup>8</sup> For example, many courts have contrasted two approaches taken with comment k. In the case-by-case approach, courts consider whether the principles of comment k should apply to the particular product in question. *See, e.g., Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 460–65 (Ct. App. 1985), *disapproved of by Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988); *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 309 (Idaho 1987); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988). In the blanket approach, courts apply the principles of comment k to all products in a particular category. *See, e.g., Brown*, 751 P.2d at 481–83; *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92–95 (Utah 1991). As will become apparent, however, this contrast in approaches is not very meaningful when analyzed with respect to whether comment k adds something to the field of products liability or is merely redundant.

<sup>9</sup> As a logical consequence, it is fair to say that comment k also contains a component requiring a reasonable alternative design. After all, a product is not *unavoidably* unsafe if it could be made safer through a reasonable alternative design.

*Duncan v. Cessna Aircraft Co.*, 665 S.W.2d 414 (Tex. 1984). The general risk-utility tests developed by these courts swallow up comment k's risk-utility test and the principles behind it. As a result, the states that have already adopted a general risk-utility test have no need to adopt comment k. In short, comment k in those states is redundant. It is only in states that continue to adhere to section 402A's consumer-expectations test that comment k provides any useful guidance—namely, by carving out an exception to the application of the consumer-expectations test for certain “drugs, vaccines, and the like” and applying the risk-utility test to those products specifically. *See* Restatement § 402A cmt. k.<sup>10</sup>

Unfortunately, many states have adopted comment k without considering its greater impact on the law of strict product liability and negligence. This has led to both misunderstanding and inconsistency as courts have considered the issue over the years.<sup>11</sup>

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<sup>10</sup> Indeed, comment k appears to be redundant even in states that retain the consumer-expectations test because it merely replicates the principles of negligence. As noted earlier, negligence is determined by weighing risk against utility. Restatement § 291 (“Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.”); *see also Carroll Towing Co.*, 159 F.2d at 173; *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 318–19 (Idaho 1987) (Bakes, J., concurring in part); Dobbs et al., *supra*, § 456. At minimum, comment k contains a risk-utility test, and often more, depending on a jurisdiction's interpretation. Thus, because negligence already covers the principles of comment k, there is no need to adopt comment k separately.

<sup>11</sup> Colorado illustrates the doctrinal confusion well. It originally adhered to the consumer-expectations test in section 402A. *See Hiigel v. Gen. Motors Corp.*, 544 P.2d 983, 987 (Colo. 1975). Then it adopted comment k on a case-by-case basis as an affirmative defense, thereby creating an exception to the consumer-expectations test for pharmaceuticals and other medical products and making the risk-utility test available for those products. *See Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 122–23 (Colo. 1983), *superseded by statute on other grounds by* Colo. Rev. Stat. § 13-22-104, *as recognized in United Blood Servs., a Div. of Blood Sys., Inc. v. Quintana*, 827 P.2d 509, 522 n.9 (Colo. 1992). A few years later, after acknowledging the problems with applying the consumer-expectations test, it adopted the risk-utility test espoused by the Supreme Court of California in *Barker*, 573 P.2d at 456, including placing the burden of satisfying the risk-utility test on the defendant. *See Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 413–14 (Colo. 1986), *overruled by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992). Considering that *Belle Bonfils* requires a defendant to satisfy the risk-utility test and show that there was no reasonable alternative design for its product, in contrast to *Barker*, which requires a defendant to satisfy only the risk-utility test, no rational defendant would elect for *Belle Bonfils*'s comment-k affirmative defense. Consequently, a few years later, *Armentrout v. FMC Corp.* overruled *Heath*, reversing the burden of proof. 842 P.2d 175, 183 (Colo. 1992). But requiring the plaintiff to satisfy the risk-utility test does nothing to resolve comment k's redundancy. A defendant moving for summary judgment, for example, could merely show that the plaintiff would be unable to satisfy the risk-utility test, a far less stringent burden than asserting comment k as an “affirmative defense”

### c. West Virginia

West Virginia has never explicitly or implicitly adopted comment k, and thus, it is in a unique position to profit from other courts' experiences over the past several decades. The *Morningstar* court, though acknowledging that its formulation of strict product liability was "not substantially different from . . . section 402A," 253 S.E.2d at 680, consciously established a standard of "not reasonably safe" in contradistinction to section 402A's standard of "unreasonably dangerous," *id.* at 683–84. In particular, it rejected the Restatement's principles by apparently endorsing a risk-utility test. *See id.* at 682. Indeed, the court specifically noted problems with the consumer-expectations test as it relates to open and obvious dangers. *See id.*

*Morningstar* was ahead of its time in explaining that "what is a defective product must be analyzed in traditional tort terminology." *See id.* at 682 (citing *Wade, supra*, at 834–35). Through subsequent interpretations of *Morningstar*, West Virginia has effectively rid itself of the need for the useless relic that is comment k. Accordingly, there is no reason to apply comment k separately in this case, as its principles have become a part of West Virginia law.<sup>12</sup> I find additional support in the fact that West Virginia courts have never discussed or applied comment k, and instead, rely solely on the law as stated in *Morningstar*. Ethicon appears to apprehend comment k's redundancy, noting that "the applicability of comment k will turn on the very same evidence necessary to establish Plaintiffs' claim that the TVT was defectively designed." (*See* Ethicon's Resp. to Pls.' Mot. for Clarification [Docket 31], at 8).

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and itself having to satisfy the risk-utility test. Colorado's struggle makes clear that comment k has no relevance in the absence of consumer-expectations.

<sup>12</sup> In *Stidham v. Boston Scientific Corp.*, No. 2:12-cv-06759, 2015 WL 2452984, at \*4 (S.D. W. Va. May 22, 2015), I noted that there was "no persuasive reason" why comment k could not be extended from prescription pharmaceuticals to prescription medical devices such as the pelvic mesh products that have been the subject of these multidistrict litigations. This was in the context of a jurisdiction that had already adopted comment k in some form, rather than in the context of a jurisdiction considering whether comment k should be adopted in the first place.



I recognize that a pair of federal district court cases predicted that the Supreme Court of Appeals of West Virginia would adopt comment k. *See Rohrbough ex rel. Rohrbough v. Wyeth Labs., Inc.*, 719 F. Supp. 470, 477 n.1 (N.D. W. Va. 1989); *Smith ex rel. Smith v. Wyeth Labs.*, No. Civ. A. 84-2002, 1986 WL 720792, at \*5 (S.D. W. Va. Aug. 21, 1986). Neither case, however, considered comment k in relation to its interplay with the overarching scheme of strict products liability. Both cases dealt with vaccines, and it made sense at the time to predict the applicability of comment k where the quintessential example used by comment k was at issue. However, with the advantage of hindsight and the opportunity to peruse the development of the risk-utility test, I easily conclude that the West Virginia Supreme Court of Appeals has not and would not adopt comment k.

The West Virginia court had the understanding and foresight to reject the consumer-expectations test and avoid the treacherous waters of comment k by crafting what is in effect a coherent risk-utility test that applies to all products. *See Morningstar*, at Syl. pt. 5. This West Virginia test has been consistently and effectively used by the courts for the past thirty-five years. I find no reason to believe that the Supreme Court of Appeals would now insert an antiquated doctrine that has “befuddled courts and scholars alike” into this state’s adequate framework for strict product liability. *See* James A. Henderson, Jr. & Aaron D. Twerski, *Will a New Restatement Help Settle Troubled Waters: Reflections*, 42 Am. U. L. Rev. 1257, 1264 (1993). Therefore, contrary to Ethicon’s argument, there is no need to consider comment k with regard to consolidation, and product warnings are relevant only to the extent they are part of the risk-utility test discussed in *Morningstar*. *See supra* at 3.

### **3. Safer Alternative Design**



Next, Ethicon asserts that a consolidated trial on design defect is improper because the plaintiff must prove the existence of a safer alternative design, which requires plaintiff-specific evidence. Specifically, according to Ethicon, the plaintiffs must show “the alternative design would have materially reduced the plaintiff’s injuries.” (Defs.’ Objection [Docket 27], at 3). First of all, “the West Virginia Supreme Court of Appeals has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product.” *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 547–48 (S.D. W. Va. 2011) (Copenhaver, J.). Admittedly, whether required or not, evidence on the existence of a safer alternative is certainly relevant, as explained in *Morningstar* Syllabus Point 5, which states that the “general state of the art of the manufacturing process” should be considered when determining whether a product is “unsafe.” *Morningstar*, 253 S.E.2d at Syl. pt. 5.

But contrary to Ethicon’s position, there is no West Virginia authority requiring plaintiffs to prove, as part of their *prima facie* case, that the proposed safer alternative design would have reduced an individual plaintiff’s specific injuries. In fact, my colleague has recently rejected this position. *See Keffer*, 791 F. Supp. 2d at 548–49 (rejecting the proposition that a plaintiff must prove that an alternative drug design would have specifically prevented her injuries (citing *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 901 (E.D. Va. 2010))). Persuaded by this reasoning, I **FIND** that plaintiff-specific information is not required to develop or defend against state-of-the-art evidence of a safer alternative design, and Ethicon’s objection is overruled.

#### **4. Federal Rules of Evidence 402 and 403**

Ethicon also argues that “a trial that attempts to determine design defect liability in the absence of individualized proof” will violate Rules 402 and 403 of the Federal Rules of Evidence. (Defs.’ Objection [Docket 27], at 3). First, Ethicon objects to the jury having to

consider the reasonableness of the TVT design at different dates corresponding to when each plaintiff received her implant surgery, a period extending over ten years. In West Virginia, the design defect inquiry focuses on the date the product at issue was marketed. *See Church v. Wesson*, 385 S.E.2d 393, 396 (W. Va. 1989) (“The question [is whether] the manufacturer use[d] reasonable care in designing and manufacturing the product at the time it was marketed . . .”). That date, October 2002, is the same for all TVT plaintiffs, regardless of when they received their surgeries. (*See* First Am. Master Long Form Compl. & Jury Demand ¶ 20). Thus, there are no risks of confusing or misleading the jury in this respect.

Second, Ethicon seems to argue that it will be prejudiced if the jury sees evidence on a “composite plaintiff” who has suffered every conceivable defect.” (Defs.’ Objection [Docket 27], at 3). As an initial matter, the court will not tolerate cumulative evidence. Furthermore, several judicially implemented safeguards are in place to protect against the prejudice that can arise from consolidation, such as carefully crafted jury instructions and special interrogatories to the jury. The limited scope of consolidation set forth herein also alleviates risks of unfair prejudice created by consolidating multiple plaintiffs. With these tools at my disposal, I am unpersuaded by Ethicon’s argument.

## **5. Fifth and Seventh Amendments**

Last, Ethicon contends that “a determination of defect liability in the first phase of trial will violate [its] constitutional rights under the Fifth Amendment’s due process clause and the Seventh Amendment’s reexamination clause.” (*Id.* at 4). This concern is unwarranted because the consolidated trial, as explained above, will not go to liability. Instead, only one element of each design defect claim will be at issue. Therefore, even if the jury finds for the plaintiffs in this initial trial phase, the plaintiffs must prove the remaining elements of their claims during the next

phase in order to hold Ethicon liable. No constitutional concerns are raised by this process. Indeed, courts often consolidate issues for trial pursuant to Federal Rule of Civil Procedure 42. *See, e.g., Wilson v. Johns-Manville Sales Corp.*, 107 F.R.D. 250, 252 (S.D. Tex. 1985) (consolidating fifty asbestos cases for trial on the issue of product defectiveness and punitive damages, which would be followed by a second phase of trial focused on the issues “peculiar to each particular plaintiff”).

### **III. Conclusion**

Finding none of Ethicon’s objections persuasive, I stand by consolidation as set forth in PTO # 184 and this Memorandum Opinion and Order, which serves as the clarification requested by the parties. The defendants’ Objection to PTO # 182 is **OVERRULED**. The Motion to Clarify [Docket 27], to the extent it seeks clarification, is **GRANTED**. And the plaintiffs’ Motion for Clarification Regarding Pretrial Order # 182 [Docket 28] is **GRANTED**.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the court’s website, [www.wvsc.uscourts.gov](http://www.wvsc.uscourts.gov).

ENTER: August 4, 2015



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE